PATENT COOPERATION TREATY

by fax and post

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

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PCT

15 MAR 2005

WRITTEN OPINION
(PCT Rule 66)

Date of mailing *(day/month/year)*	28.05.2004
Applicant's or agent's file reference 08-892370WO	**REPLY DUE** **within 3 month(s)** from the above date of mailing

International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA 03/00964	27.06.2003	28.06.2002

International Patent Classification (IPC) or both national classification and IPC
A01H5/00, A01H5/00

Applicant
UNIVERSITY OF GUELPH et al.

1. This written opinion is the **first** drawn up by this International Preliminary Examining Authority.

2. This opinion contains indications relating to the following items:

I	☒	Basis of the opinion
II	☐	Priority
III	☒	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
IV	☐	Lack of unity of invention
V	☒	Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
VI	☐	Certain documents cited
VII	☐	Certain defects in the international application
VIII	☐	Certain observations on the international application

3. The applicant is hereby **invited to reply** to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(d).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also: For an additional opportunity to submit amendments, see Rule 66.4.
For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4 bis.
For an Informal communication with the examiner, see Rule 66.6.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.

4. The final date by which the international preliminary examination report must be established according to Rule 69.2 is: 28.10.2004

Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Burkhardt, P Formalities officer (incl. extension of time limits) Büchler, S Telephone No. +49 89 2399-8090

I. Basis of the opinion

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed")*:

Description, Pages

1-36 as originally filed

Sequence listings part of the description, Pages

1-10 as originally filed

Claims, Numbers

1-26 as originally filed

Drawings, Sheets

1/13-13/13 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
   ☐ the language of publication of the international application (under Rule 48.3(b)).
   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☒ contained in the international application in written form.
   ☒ filed together with the international application in computer readable form.
   ☐ furnished subsequently to this Authority in written form.
   ☐ furnished subsequently to this Authority in computer readable form.
   ☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
   ☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:
   ☐ the claims, Nos.:
   ☐ the drawings, sheets:

5. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been and will not be examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 1 - 26 (all partially)

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 1 - 26 (all partially)

2. A written opinion cannot be drawn due to the failure of the nucleotide and/or amino acid sequence listing to comply with the Standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	
Inventive step (IS)	Claims	1 - 26: No
Industrial applicability (IA)	Claims	

2. Citations and explanations

see separate sheet

Re Item III
No opinion

1. In response to an invitation of the ISA to restrict the claims or pay additional search fees the applicant neither restricted the claims nor paid additional fees. Consequently, only invention 1 was searched and the written opinion will also be limited to invention 1.

2. The reasons for the non-unity objection were as follows:

2.1 Article 3(4)iii PCT and Rule 13.2 PCT stipulate that where a group of inventions is claimed the requirements of unity shall be fulfilled only where there is a technical relationship among those inventions involving one or more of the same corresponding special technical features. "Special" technical features are those features that define a contribution which each of the inventions makes over the prior art.

2.2 The only corresponding technical feature linking the different groups of inventions is that they all relate to genes form *Medicago sativa* that are allegedly harvest-inducible. Such genes, however, are already known from the prior art (e.g. WO0173090). Therefore, this feature cannot provide a common inventive concept for potential inventions 1 - 3.

2.3 The applicant was requested to note that the alleged function of an gene, i.e. being harvest-inducible, is a non-distinctive characteristic and would not render the subject-matter of claim 1 novel over the prior art.

2.4 Consequently, there is lack of unity, and the different inventions not belonging to a common inventive concept, had been divided into different groups pursuant to Article 17(3)(a) PCT:

Invention 1 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:1), the corresponding regulatory element (SEQ ID NO:4), a method for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous

proteins in plants employing said regulatory element.

Invention 2 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:2), the corresponding regulatory element (SEQ ID NO:5), methods for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Invention 3 (Claims 1 - 26, all partially)

relating to a harvest-inducible cDNA (SEQ ID NO:3), the corresponding regulatory element (SEQ ID NO:6), methods for their isolation, vectors and plants containing said regulatory element and to methods for the production of heterologous proteins in plants employing said regulatory element.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

The following documents (D) are referred to; the numbering is following the order of the International Search Report:

D1 Ferullo *et al.*, 1996. Crop Sci 36:1011-1016.
D2 Matz and Lukyanov, 1998. Nucl. Acids Res. 26:5537-5543.
D3 Kuhn, 2001. Ann. Bot. 87:139-155.
D4 WO-A-0173090 (Samuel Roberts Noble Foundation)

1. **Article 33(2)(3) PCT (Novelty and inventive step)**

1.1 Present claim 1 is directed to method for isolating a harvest-inducible DNA sequence by differential screening.

1.2 Document D1 discloses proteins from alflafa that accumulate after harvest and

provides an incentive for the isolation of their their cDNAs and the corresponding promoters (page 1016, column 1 2nd paragraph).

1.3 A man skilled in the art in need of a method to isolate cDNAs and promoters that are differentially regulated would turn to D2 or D3, both describing strategies for differential screening. He thus would arrive at the subject-matter of present claim 1 without the need for an inventive effort. The same holds true for dependent claim 2 and for claims 4 - 6. Claims 1, 2 and 4 - 6 do not meet the requirements of Article 33(3) PCT.

1.4 Present claim 3 is directed to a putative harvest-inducible cDNA sequence consisting of SEQ ID NO:1, fragments thereof or sequences and fragments that hybridise under stringent conditions to SEQ ID NO:1.

1.5 It is not apparent form the description that a fragment of SEQ ID NO:1 would solve the technical problem, i.e. the provision of a harvest-inducible cDNA sequence. Present claim 3 does therefore not meet the requirements of Article 33(3) PCT.

1.6 The same holds true for present claim 7 directed to a fragment of a harvest-inducible regulatory element and for present claims 8 - 26 depending on or relating to claim 7. Claims 3 and 7 - 26 do not meet the requirements of Article 33(3) PCT.

2. Concluding remarks:

2.1 The attention of the Applicant is drawn to the fact that the application may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed, Article 34(2)(b) PCT.

2.2 In order to facilitate the examination of the conformity of the amended application with the requirements of Article 34(2)(b) PCT, the applicant is requested to clearly identify the amendments carried out, irrespective of whether they concern amendments by addition, replacement or deletion, and to indicate the passages of the application as filed on which these amendments are based

(see also Rule 66.8(a) PCT): If the applicant fails to provide these indications the amendments will not be taken into account for the international preliminary examination report

2.3 If the applicant regards it as appropriate these indications could be submitted in handwritten form on a copy of the relevant parts of the application as filed. Please note that under Rule 11.9 (a) PCT only typed or printed amendments are acceptable.